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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,529	09/22/2003	Marc E. Surette	3009-P02297US2	9936

110 7590 06/01/2006

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,529	SURETTE, MARC E.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's petition to revive the application, amendment and response filed on August 8, 2005 has been received and entered into the case. The petition was granted on November 4, 2005. Thus, claims 8 – 14 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Objections

Claim objections are withdrawn due to amendment.

Claim Rejections - 35 USC § 112

Rejections under 35 U.S.C. 112, second paragraph, are withdrawn due to amendment.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 8 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger et al. (US 4999380) in view of Klor et al. (US 5886037) and/or Loria (WO 93/21774).

Applicant claims a method for treating hypertriglyceridemia, the method comprising administering an effective amount of a composition comprising fatty acyl compounds, wherein the fatty acyl compounds have a polyunstaruated fatty acid content of at least 65%; and includes about 10 – 35% linoleic acid, about 5 – 50% gamma linolenic acid, about 15 – 60% alpha linolenic acid, and about 15 – 55% stearidonic acid; and optionally in combination with a therapeutic agent selected from an antilipemic, antioxidant or antidiabetic agent. The composition is administered in an amount that delivers about 0.04 – 0.35 grams of fatty acyl compounds per kilogram of patient body weight per day. The composition is administered orally and in a single dose.

Berger teaches a method for treating hyperlipidemia (or hypretriglyceridemia) (col.1 line 44-64), comprising administering a composition of blackcurrant seed oil, which comprises 45% linoleic acid, 17% gamma linolenic acid, 13% alpha linolenic acid and 3.5% stearidonic acid (col.2 line 45-60). The composition is administered orally in a single dose of 1 – 25g (claims).

Berger does not teach the method wherein the composition comprises the exact percents of fatty acids, or wherein the dose is administered as claimed. However, the disclosed percent of fatty acids do overlap or are close to the claimed amounts. In addition, Klor and Loria teach methods for treating increased serum lipids (hypertriglyceridemia) by administering varying dosages of compositions comprising varying percents of fatty acyl compounds. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the effective amounts of fatty acids and dosages of Berger as a matter of routine experimentation, as evidenced by Klor and/or Loria. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Berger, Klor and/or Loria, to optimize the

dosages and percentages of fatty acyl compounds of Berger with a reasonable expectation for successfully treating hypertriglyceridemia.

3. Claims 8 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger in view of Klor and/or Loria, and further in view of Coupland (US 6340485 B1).

Applicant claims a method for treating hypertriglyceridemia, the method comprising administering an effective amount of a composition comprising fatty acyl compounds, wherein the fatty acyl compounds have a polyunstaruated fatty acid content of at least 65%; and includes about 10 – 35% linoleic acid, about 5 – 50% gamma linolenic acid, about 15 – 60% alpha linolenic acid, and about 15 – 55% stearidonic acid; and optionally in combination with a therapeutic agent selected from an antilipemic, antioxidant or antidiabetic agent. The composition is administered in an amount that delivers about 0.04 – 0.35 grams of fatty acyl compounds per kilogram of patient body weight per day. The composition is administered orally and in a single dose. The single dose comprises Echium oil, the composition delivers about 15 g Echium oil per day, and the polyunsaturated fraction is concentrated.

Berger teaches a method for treating hyperlipidemia (or hypretriglyceridemia) (col.1 line 44-64), comprising administering a composition of blackcurrant seed oil, which comprises 45% linoleic acid, 17% gamma linolenic acid, 13% alpha linolenic acid and 3.5% stearidonic acid (col.2 line 45-60). The composition is administered orally in a single dose of 1 – 25g (claims).

Berger does not teach the method wherein the composition comprises the exact percents of fatty acids, or wherein the dose is administered as claimed. However, the disclosed percent of fatty acids do overlap or are close to the claimed amounts. In addition, Klor and Loria teach

methods for treating increased serum lipids (hypertriglyceridemia) by administering varying dosages of compositions comprising varying percents of fatty acyl compounds. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize the effective amounts of fatty acids and dosages of Berger as a matter of routine experimentation, as evidenced by Klor and/or Loria. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Berger, Klor and/or Loria, to optimize the dosages and percentages of fatty acyl compounds of Berger with a reasonable expectation for successfully treating hypertriglyceridemia.

Berger does not teach the method wherein the fatty acid composition comprises Echium oil. Howevever, Coupland teaches Echium oil contains the same fatty acids in similar and/or overlapping amounts to that of blackcurrant seed oil. Specifically, Coupland teaches that Echium oil comprises about 10 – 20% linoleic acid, about 5 – 12% gamma linolenic acid, about 28 – 50% alpha linolenic acid, and about 5 – 20% stearidonic acid (table 2). At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use Echium oil in the methods of Berger, since it was known to contain the same fatty acids at similar amounts to the blackcurrant seed oil of Berger, as evidenced by Coupland. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Coupland to use Echium oil in the methods of Berger with a reasonable expectation for successfully treating hypertriglyceridemia.

Although the references do not teach administering 15 g Echium oil per day, or wherein the fatty acid fraction is concentrated, it would have been obvious to one of ordinary skill to optimize the dose and fatty acid content in accordance with the methods of Berger as a matter of

standard practices and experimentation. As such, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by standard practice to optimize the concentration of Echium oil and dosages of Coupland and use the obtained oil in the methods of Berger with a reasonable expectation for successfully treating hypertriglyceridemia.

Response to Arguments

Applicant argues that Berger does not teach treating hypertriglyceridemia, but that LDL is reduced and HDL is increased; that Berger may teach treating some diseases that may have elevated triglyceride levels but does not teach treating hypertriglyceridemia, per se; and that the references do not teach the effect of the compositions on triglyceride levels; or the claimed amounts of PUFAs. Applicant argues against the references individually in that they teach different amounts of PUFAs and that the amounts disclosed do not overlap or even come close to the claimed amounts. Finally, applicant argues that Coupland does not cure the deficiencies of Berger, Klor and/or Loria.

However, these arguments fail to persuade because hypertriglyceridemia is defined as having elevated triglyceride concentration in the blood. Berger teaches treating patients with conditions that are characterized by increased levels of triglycierides (col.1) and treating lipoprotein disorders associated with cholesterol metabolism (claims), which may include hypertriglyceridemia. Thus, while the reference does not specifically teach, or anticipate, treating hypertriglyceridemia, the reference certainly would suggest to one in the art that

hypertriglyeridemia could be treated by administering the instant PUFAs, with a reasonable expectation of success.

Regarding the amounts of each PUFA, the claims are drawn to amounts at about particular ranges. Thus, the claims allow for some degree of modification of the ranges. Furthermore, the claims are to very broad ranges of each PUFA, indicating that some degree of optimization may occur and still be effective. The cited references teach the claimed PUFAs in amounts that overlap with several of the PUFAs (gamma and alpha linolenic acids) and are reasonably close to the ranges of others (linoleic, stearidonic). Moreover, the cited references clearly demonstrate that variations in the amounts of each PUFA may result in treating hypertriglyceridemia and that one in the art would recognize that such amounts can be optimized with a reasonable expectation for successfully treating hypertriglyceridemia.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding Coupland, the reference is relied upon to demonstrate that Echium oil was known to contain the claimed amounts of PUFAs. Thus, as stated above and is reiterated here, it would have been obvious to one of ordinary skill in the art to use Echium oil in the methods of Berger with a reasonable expectation for successfully reducing elevated triglyceride levels, or treating hypertriglyceridemia.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 17, 2006
AU 1651

RUTH A. DAVIS
PATENT EXAMINER